

**K202876 Confirm Rx Insertable Cardiac Monitor**Dec 1, 2020  
64 days to decisionK202876 · Product code: **MXC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k202876/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Sep 28, 2020
Decision date	Dec 1, 2020
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott (St. Jude Medical)</b>
Location	Sylmar, CA, US
Contact	Juni Sarkar
510(k) history	6 submissions · 6 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202876/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026